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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,650	07/11/2000	Kenneth F. Buechler	071949-1307	9972

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

10

DATE MAILED: 03/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-17

Office Action Summary

Application No.

09/613,650

Applicant(s)

Buechler

Examiner

LYLE A ALEXANDER

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-91 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 74-91 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claim Rejections - 35 USC § 112

Claims 74-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 74 lines 3-4 claims a "smooth or a nonporous textured surface ... comprising depressions and/or protrusions extending between 1nm and 0.5mm ...". This is confusing because if the surface is smooth, then it will not have the protrusions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 74-91 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Grenner et al.

Grenner et al.(USP 5,051,237) teach an assay device having projections(22) and a plurality of discrete reaction zones for capture of the analyte of interest. The reaction zones contain immobilized antibodies.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 74-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watts et al. or Sutton et al.

Watts et al. teaches a non-capillary assay using a matrix of non-porous beads wherein the beads will have a number of specific binding pair(sbp) members affixed to their surface which are capable of binding a complementary sbp on the analyte of interest. The sbp have been read on the claimed "capture zones". In column 2 the beads are taught as ranging from .2-2.5 mm in diameter. In columns 3-4 lines 68- 5 respectively teach the beads are made of the claimed latex, metal sols and polystyrene materials. Column 4 lines 30+ teach the sbp may be specific for nucleic acids . Column 9 lines 64-65 teach the beads may have a roughened surface. Watts et al. is silent to the degree of surface roughness and specifically to the claimed 1nm-0.5mm protrusions representing the surface roughness.

Sutton et al. teach a non-capillary assay for nucleic acid detection and amplification. Column 3 lines 39-43 teach "... the support surface be roughened in some fashion to facilitate adhesion of the nucleic acid compositions". Column 4 teaches the support can be impermeable and non-swellable beads in aqueous solutions. Sutton

et al. is silent to the degree of surface roughness and specifically to the claimed 1nm-0.5mm protrusions representing the surface roughness.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable has predictable and well known results. The extent of the surface roughening would have been expected to be a result effective variable.

Both Watts et al. and Sutton et al. teach it is known and desirable to roughen the surface. It would have been within the skill of the art to modify both Watts et al. and Sutton et al. and roughen the surface to the claimed 1nm-0.5mm protrusions as optimization of a result effective variable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A ALEXANDER whose telephone number is 703-308-3893. The examiner can normally be reached on MONDAY,WEDNESDAY,FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on 703-308-4037.



LYLE A ALEXANDER
Primary Examiner
Art Unit 1743

March 10, 2002